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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,828	VIRCA ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Claims 1-30 are currently pending in this application.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 71-100 have been renumbered 1-30.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 14, 27 and claims 2-13, 15-26, 28-30 which depend from claims 1, 14, and 27 respectively are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 14, 27 recite the phrase "a method of screening a candidate molecule to identify its ability…". While Examiner understands that applicants are claiming a method of

identifying candidate compounds for its ability to agonize or antagonize the polypeptides of the invention, the above recitation "a method of screening a candidate molecule to identify its ability..." is a little confusing. Examiner requests applicants to clarify the above phrase by amending the above recitation as "a method of screening a candidate molecule to identify/determine its ability...".

Claims 1, 14, 27 and claims 2-13, 15-26, 28-30 which depend from claims 1, 14, and 27 respectively are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 14, 27 recite the phrase under part (b) "determine the level of a biological activity in the medium". First of all it is not clear as to whose biological activity applicants are referring to. It appears that applicants are referring to the biological activity of the polypeptide. However, the way the claim is written it becomes unclear as to whether applicants are referring to the biological activity of the polypeptide or the candidate compound that is being tested..

Claims 1, 14, 27 and claims 2-13, 15-26, 28-30 which depend from claims 1, 14, and 27 respectively are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 14, 27 recite the phrase "biological activity". It is not clear to the Examiner as to which activity of the polypeptide applicants consider as biological activity. The metes and bounds of the phrase is not clear to the Examiner. A perusal of the specification did not provide a specific definition for the above phrase.

Claims 8-9, 21-22, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8-9, 21-22, 30 are directed to the medium comprising the substrates for the polypeptide that is being tested. However, a perusal of the specification does not provide any specific substrates for the polypeptide that is being tested except for the fact that it is a kinase enzyme. It is well known in the art that kinases can be highly specific with highly specific substrates. The specifcation fails to provide any such specific substrates for the enzyme polypeptide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening a candidate molecule as an antagonist or an agonist of the polypeptide by determining the ability of the compound to modulate the phosphorylation --of its specific substrate-- activity of the polypeptide, does not reasonably provide enablement for any such method wherein any substrate is used in such a phosphorylation assay and wherein any biological activity of the polypeptide (such as cell proliferation or apoptotic death) is used for the above assay. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-30 are so broad as to encompass a method of identifying candidate compounds which modulate the phosphorylation activity of the polypeptide using any substrate or using any activity of the polypeptide apart from the specifically identified activity, i.e., phosphorylation activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of substrates broadly encompassed or the number of activities of the polypeptide encompassed by the claims. Since it is well k known in the art that kinases have specific substrates and not all substrates can be phosphorylated by all or any kinase/s, using any or all substrates for such a method as above, requires a knowledge of and guidance with regard to the way the assay needs to be performed. Similarly, use of any other activity by the polypeptide such as cell proliferation activity or apoptosis activity requires setting up of proper assay procedures such that it does not result in false positive or false negative results. For example, the candidate compounds themselves may induce cell proliferation or cell death without the involving the polypeptide that is being tested. Therefore use of any activity of the polypeptide other than phosphorylation activity requires a knowledge of and guidance with regard to setting up and interpretation of results of such assays. However, in this case the disclosure is limited to the phosphorylation assay of some substrates. In view of

the lack of guidance it would require undue experimentation by the skilled artisan to make and use the claimed method. The specification is limited to teaching that the polypeptide is a kinase but provides no guidance with regard to methods of identification of compounds that can modulate its activity. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

The specification does not support the broad scope of the claims because the specification does not establish: (A) a rational and predictable scheme for identifying compounds which modulate the phosphorylation activity of the polypeptide using any polypeptide as substrate (B) a rational and predictable scheme for identifying compounds as modulators using any activity of the polypeptide (other than phosphorylation activity); and (C); the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of compounds having the desired characteristics is unpredictable and the

experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 8-9, 13, 21-22, 26, 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-9, 13, 21-22, 26, 30 are directed to a method involving the use of polypeptides as substrates whrein said polypeptides comprise a recognition comprising recognition motif comprising a serine, threonine, and/or tyrosine and use of natural or modified enzymes, substrates, ligands or receptors , mimetics, catalytically inactive mutants of the polypeptide, and peptides and antibodies that bind to the polypeptide as candidate molecules. Claims 8-9, 13, 21-22, 26, 30 are rejected under this section of 35 USC 112 because the claims are directed to the use of a genus of polypeptides derived including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution, and fragments of such polypeptides that have not been disclosed in the specification. No description has been provided of all polypeptide sequences encompassed by the claim. No information, has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure/function of all the polypeptide sequences within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures and functions. Therefore many structurally and functionally unrelated polypeptides are

encompassed within the scope of these claims. The specification does not disclose even a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

Manjunath N. Rao
May 23, 2003

MANJUNATH RAO
PATENT EXAMINER